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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,481	06/20/2001	Takao Hamakubo	P21128	9557

7055 7590 11/15/2005

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,481

Applicant(s)

HAMAKUBO ET AL.

Examiner

M. Franco Salvoza

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-6 and 15-28 were amended, with claims 1, 2, 21 and 25 being independent claims. Claims 1-8 and 15-28 are pending and under consideration.

Response to Brief Summary of Interview

Based on the telephone conference of August 9, 2005, it was believed that the applicant and Office agreed that if the claims were amended to recite a method for recovering budded baculovirus that did not utilize recovery of proteins via surface display technology that the application would be placed in condition for allowance. However, it appears that what was agreed to in the telephone conference was not reflected in the claim amendments.

Based on applicant's last written response received August 31, 2005, applicant argues that because the organelle membrane-bound protein is recovered from the viral envelope of the budded baculovirus, the protein is not fused to the coat protein of the virus or the cell membrane of the host cell. Applicants also noted that the prior art of record does not teach or suggest the recovery of a budded baculovirus expressing an intracellular organelle membrane-bound protein, and that the unfused proteins are inherently supported by applicant's original filed disclosure.

Applicant's arguments are considered but found unpersuasive. First, the protein is fused to the polyhedrin promoter, as is conventional in the baculovirus art. (see page 9 of the specification). Additionally, the disclosure does not teach an unfused protein. Please review Office Action mailed May 3, 2005, wherein applicant's incorporation of "unfused" was found to be NEW MATTER.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 15-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lanford et al., Possee et al., Nohturfft et al., and Duncan et al.

Applicant reiterated the incorporation by reference to its previous set of arguments. The rejection is maintained for reasons of record because Lanford et al. teaches the use of the baculovirus expression system to express a gene product. The Possee et al. reference teaches the motivation for expressing any protein of interest within a baculovirus within the first full paragraph of the second column on page 570. Nohturfft et al. and Duncan et al. teach expression of the protein of interest, SREPB-Z, in both the Endoplasmic Reticulum and Golgi Apparatus, respectively.

One of ordinary skill in the art at the time the invention was made would have combined the Lanford et al. reference with Possee et al. in further view of Nohturfft et al. and Duncan et al. to separate, i.e., recover, a budded baculovirus expressing an intracellular organelle membrane-bound protein. The combination of references teaches expression of an intracellular organelle membrane-bound protein on the coat of a baculovirus. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success, according to the Lanford et al. reference. The Lanford et al. reference also points to a reasonable expectation of success, since the level of nonfusion proteins created by nonfusion vectors is comparable to the level of fusion proteins created by fusion vectors, see Lanford et al. pp. 1555-1556.

In conclusion, all of the limitations required by the amended claims are expressly taught by the references, and the rejection is maintained for reasons of record.

The presently claimed invention via claim amendments in 1-8 and 15-28 does not distinguish from the baculovirus expression system and surface display technology as is conventional in the art. Please see the attached reference from Fields, *Virology*, Third Edition, Volume 1, p. 539, which illustrates the baculovirus replication cycle where expressed proteins travel to the plasma membrane for budding and recovery.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



M. Franco Salvoza
Patent Examiner


SHANNON FOLEY
PRIMARY EXAMINER